Subject: FDA releases guidance clarifying FDA and EPA Jurisdiction Over Mosquito-Related Products

THE FOLLOWING IS INTENDED FOR BACKGROUND USE ONLY. EMBASSY OFFICERS SHOULD NOT APPROACH HOST GOVERNMENTS REGARDING THIS GUIDANCE, BUT ONLY TO RESPOND TO INQUIRIES, IF ASKED. OFFICIAL REQUESTS FOR INFORMATION SHOULD BE REFERRED TO FDA: Ex. 5 - Deliberative Process

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Dear All:

On October 5, 2017, the U.S. Food and Drug Administration (FDA)/Center for Veterinary Medicine published a new final guidance: Guidance for Industry #236: *Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products*. It provides information regarding FDA and U.S. Environmental Protection Agency (EPA) jurisdiction over the regulation of mosquito-related products, including those produced through the use of biotechnology, such as the Oxitec genetically engineered (GE) mosquito.

The link to FR notice: [HYPERLINK "https://www.federalregister.gov/documents/2017/10/05/2017-21494/guidance-clarification-of-the-food-and-drug-administration-and-environmental-protection-agency"]

FDA developed this guidance in coordination with the EPA and published a draft, "Regulation of Mosquito-Related Products," for public comment in January 2017, which were considered before releasing this final guidance.

The final guidance states that:

- Mosquito-related products that are intended to reduce the pathogen carrying ability of mosquitoes and/or to prevent mosquito-borne diseases in humans or animals are subject to FDA's regulatory authority.
- Mosquito-related products intended to reduce mosquito populations are under the regulatory jurisdiction of EPA.

The link to Final Guidance: [HYPERLINK "https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM533600.pdf"]

This guidance will result in the jurisdiction for the regulation of the Oxitec GE mosquito (OX513A *Aedes aegypti* mosquito) moving from FDA to EPA.

NOTE: We do not anticipate the release of this guidance to raise concerns among other governments or to have any impacts on agricultural trade, but we want you to be aware of its release. Please note that this guidance is not intended set any regulatory precedents for other insects created via biotechnology that may have agricultural applications.

As part of the [HYPERLINK "https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GEPlants/UCM537311.pdf"], the FDA, along with the EPA and USDA, committed to clarifying how the U.S. federal government intends to

regulate genetically altered insects. This final guidance fulfills part of that overarching commitment. It does not reflect how all insects developed using biotechnology will be regulated.

ACTION REQUEST: Please report to FAS New Technologies and Production Methods Division staff Diane Wray-Cahen ([HYPERLINK "mailto:Diane.Wray-Cahen@fas.usda.gov"]) if there are any reactions or responses publication to this guidance in your country(ies) from the government or the press.

Please let me know of any if you have any questions.